



4518 '99 APR -7 AS:57



March 25, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement, CellaseneTM, within the last thirty days under the Sundown brand name. Cellasene contains the following ingredients: Borage (seed oil), Bladderwrack Extract, Fish Oil, Grape Seed Extract, Soya Lecithin, Sweet Clover Extract and Ginkgo Biloba Extract. It bears the following statement(s) on the label and/or in the labeling:

[It] helps eliminate cellulite.

- ...deal with cellulite at its source...
- ...work below the surface of your skin where cellulite begins.
- ...scientifically formulated to help eliminate cellulite.
- ...works over time at the source of the problem to eliminate cellulite.
- ...increase blood circulation, reduce fluid buildup, stimulate metabolism and reduce localized fats.

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The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Detrai Suur Broke

Vice President of Regulatory Affairs and Assistant General Counsel

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Enclosure